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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,290	03/20/2001	D. Wade Walke	LEX-0151-USA	1779

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EXAMINER

CHISM, BILLY D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,290

Applicant(s)

WALKE ET AL.

Examiner

B. Dell Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 11-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

This Office Action is in response to Paper No.13, filed 20 February 2003. Claims 5-10 are canceled. Claims 1-4 and new claims 11-12 are currently under consideration by the Examiner.

Withdrawal of Objections and Rejections

1. The rejections and/or objections made in the prior office action, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections and Objections (New and/or Maintained)

Claim Rejections - 35 USC § 112

2. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 is rejected for the indefinite recitation of the phrase "comprising [a] nucleic acid sequence of Claim 4." As stands now, the instant claim connotes some part of the sequence of the nucleic acid sequence of Claim 4. As indicated by the brackets above, the claim should be amended to delete "a" and insert "the". Thus, the phrase above should read, "comprising [a] the nucleic acid sequence of Claim 4."

Claim Rejections - 35 USC § 101

3. (Maintained) Claims 1-4 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well

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established utility. Applicants argue that: (i) the homology of the claimed sequence to that of human semaphoring; and (ii) utility of the sequences as DNA Chips.

4. These arguments have been fully considered, but are not deemed persuasive as explained in the following:

(i) Similarity or homology does not capitulate function as is concluded in Bork 2000 (*Powers and Pitfalls in Sequence Analysis: The 70% Hurdle*, Genome Research, 2000, 10:398-400). Bork discusses the limitations of gene expression data extrapolation and that mere homology does not necessarily yield similar activity even in the protein products. Thus, without disclosure in the specification as to the biological activity of the claimed sequence being that of the human semaphorin, there is nothing to establish that homology or similarity capitulate similar or exact biological activity, thus, there is no established specific and substantial utility.

(ii) The use or utility of the claimed sequence as a DNA chip does not meet the requirement of a specific and substantial asserted utility. If Applicants were able to establish that the protein encoded for by the polynucleotide of the present invention was a semaphorin protein with respects to biological activity, then further characterization would be acceptable. However, Applicants have failed to make this association. Such uses as "for DNA chips" or for chromosome mapping is, again, neither a specific, nor substantial utility since any nucleotide sequence can be used in such an assay. While it is clear that the nucleic acid molecule of the present invention would hybridize to a chromosome, without knowing the function of the protein encoded for by this nucleic acid molecule, then simply identifying that a nucleic acid molecule localizes to a

particular region of a chromosome would not provide a use for the nucleic acid molecule of the present invention.

(iii) The use or utility of the claimed sequence for the exon information does not meet the requirement of a specific and substantial asserted utility, wherein if there is no knowledge of what the function of the actual sequence, regardless of the basis of homology, then there is no asserted utility. The Examiner is not detracting from the importance of exon information regarding the genome, however, the Examiner is stating that without an established biological activity for the claimed sequence and the function of the protein product, there is no more purpose for this exon than that information that currently exists for other exons known in the art.

5. Claims 1-4 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. New claims 11-12 are rejected under the above 35 USC 101 and 35 USC 112, first paragraph, and following the same reasoning as above. Since the nucleic acid molecule comprising SEQ IS NO: 1 is rejected for lacking utility, then it reasonably follows that the expression vector and cell comprising the expression vector would be lacking utility. This rejection was necessitated by amendment.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


B. Dell Chism
19 May 2003


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600